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| 10/582,612  | 04/16/2007  | Hideki Harada        | 2006_0867A          | 2018             |
| 513 7590 02/17/2011<br>WENDEROTH, LIND & PONACK, L.L.P.<br>1030 15th Street, N.W.,<br>Suite 400 East<br>Washington, DC 20005-1503 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| TRAN, THO Q   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 4165  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/582,612

**Applicant(s)**

HARADA, HIDEKI

**Examiner**

THO TRAN

**Art Unit**

4165

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### ***Specification***

1. The disclosure is objected to because of the following informalities:
  - a. page 10, line 4 and page 24, line 8 - "prove" should be changed to "probe"
  - b. page 16, line 8, "to" should be changed to "top"
  - c. page 27, line 2, "fores" should be changed to "forced"Appropriate correction is required.

#### ***Claim Objections***

2. Claims 2, 4, and 7 are objected to because of the following informalities:
  - d. Use of the term "it" in claims 2 and 4 should be avoided for clarity. The term "it" should be replaced with a more specific reference in all instances.
  - e. For claim 7, the term "prove" should be replaced with "probe" for clarity.Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 12 specify that the probe holding member should be a size that would permit positioning between a temporal muscle and a temporal bone. However, the language of the claim as written is indefinite as to what size limitation(s) the probe holding member in both claims could take on.

5. Claims 17 – 19 are rejected under 35 U.S.C. 112, 4<sup>th</sup> paragraph, as being improper dependent claims for failing to include all the limitations of the claim upon which it depends and for failing to further limit the subject matter of the claim upon which it depends. Specifically, claim 17 (and the two dependent claims 18 and 19) only requires the process steps of obtaining a master model which corresponds to a space defined by and between a temporal bone and a temporal muscle, and then molding a plastic material based on the obtained master model and does not require the structure of a probe holding device which includes a probe holding member of claim 1. Applicant should consider amending claims 17 - 19 so that it does not include any reference to claim 1. As the Federal Circuit treats non-compliance with 35 USC 112 4th paragraph as a patentability issue, it is considered more appropriate to treat a claim that does not comply with 35 USC 112 4th paragraph by rejecting the claim under 35 USC 112 4th rather than by objecting to such claim under 37 CFR 1.75(c) as provided for in MPEP 608.01(n)(II). See *Pfizer Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6, 8, 10, 11, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Njemanze (U.S. patent no. 6,547,737).

8. Regarding claim 1, Njemanze discloses a probe holding device which includes a probe holding member for holding a blood flowmeter probe and which is used with the blood flowmeter probe when intracerebral blood flow is measured, wherein the probe holding member is allowed to be disposed in a position of being adjacent to and outside a temporal bone while the blood flowmeter probe is held by the member (see Figure 1 and column 4, lines 3 – 11).
9. Regarding claim 2, Njemanze discloses the device comprises two probe holding members (see two temporal arms of device in Figure 1 and column 4, lines 4 - 6), and it further comprises a bridging part (see central arm in Figure 1 and column 4, lines 4 – 6) which bridges said probe holding members together. The term "it" was interpreted to mean the device according to claim 1.
10. Regarding claim 6, Njemanze discloses the device is formed of a plastic material (see column 4, lines 19 -21).
11. Regarding claim 8, Njemanze discloses the probe holding member is able to hold also a temperature sensor. In figure 1 of the Njemanze patent, mounting points are provided for up to two probes. One mounting point could be used to hold a flow meter and the other could be used to mount a temperature sensor.
12. Regarding claim 10, Njemanze discloses the blood flowmeter probe is a probe for the ultrasonic-Doppler flowmetry (see column 1, lines 39 – 42).
13. Regarding claim 11, Njemanze discloses the probe holding member has a size which allows the member to be positioned between a temporal muscle and a temporal

bone (see Figure 1, device is sized such that it is capable of performing the intended use noted in the claim).

14. Regarding claim 12, Njemanze discloses the probe holding member has a size which allows the member to be positioned between a temporal muscle and a temporal bone of a rat or a mouse (see Figure 1 and column 4, lines 21 – 23).

15. Regarding claim 14, Njemanze discloses a blood flow measuring device which comprises (1) the probe holding device according to claim 1 (see Figure 1), and (2) the blood flowmeter probe (see Figures 2 and 3).

16. Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Clynych (U.S. patent no. 6,463,351).

17. Regarding claim 17, Clynych discloses a production process capable of forming the probe holding device of claim 1 (see Technical Field in column 1). Clynych discloses a method comprising obtaining a master model which corresponds to a space defined by and between a temporal bone and a temporal muscle (see Figure 1, steps 20, 22, 24, 26, 30, 28, 32, 34, 36, 38) and then, molding a plastic material based on the obtained master model (see Figure 1, step 40).

18. Regarding Claim 18, Clynych discloses that the method can be adapted to form any anthropometric device where a precision fit to the human body is required (see column 4 lines 40 – 44). It follows that the method is flexible enough to fabricate the probe holder described in claim 17. Clynych discloses that that the master model is obtained by pouring a curable material into the space followed by curing the curable material in the space (see column 5, lines 15 – 49).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 3, 4, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Njemanze (U.S. patent no. 6,547,737) in view of Percy (U.S. patent no. 6,421,837).

22. Regarding claim 3, Njemanze discloses the limitations of claim 2 (see paragraph 9 above). However, Njemanze does not disclose that the probe holding members and the bridging part are in the form of a sheet respectively, and an edge portion of each probe holding member is connected together to either edge portion of the bridging part. Percy teaches a headband comprising a top portion and two side portions (see Figure 1, items 12, 14, & 18 and column 2, lines 21 - 22). The portions are in the form of sheets and are connected together along the edges of each portion (see Figure 1). It would have been obvious to a person of ordinary skill in the art at the time of the

invention to modify the shape of the central and temporal arms of the Njemanze probe holder to conform to the sheet shape of the Pearcy headband because headbands are relevant art for fixtures that can be adapted for mounting probes on the head.

23. Regarding claim 4, Njemanze also discloses that the cross section of the device has a U-shape cross section in which the bridging part corresponds to a bottom bar of the U-shape cross section and the probe holding members correspond to legs of the U-shape cross section which extend from both ends of the bottom bar (see Figure 1). Additionally, for purposes of examination, the term "it" was interpreted to mean "the device according to claim 3."

24. Regarding claim 5, Njemanze also inherently discloses that the U-shape cross section can be provided by folding a sheet material. In column 4, lines 19 – 23, Njemanze states that the material of the hanger (probe holder) could be made of a lightweight thermoplastic with considerable flexibility to accommodate different head sizes. Because Njemanze also discloses a hanger with a u-shape cross section, it is logical to conclude that the U-shape can be formed by folding the flexible plastic material.

25. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Njemanze (U.S. patent no. 6,547,737) in view of Hon (U.S. patent no. 4,947,853). Njemanze discloses a probe holding device which includes a probe holding member (see paragraph 7 above). However, Njemanze does not disclose that the probe holding member has a concave portion which is complementary to the form of the probe so that the probe can be fitted into the concave portion. Hon teaches a probe holding device



wherein the probe holding member has a concave portion (see Figure 3 and column 2, lines 45 - 49). The concave portion is capable of accommodating the relevant sensor probe. It would have been obvious to a person having ordinary skill in the art to modify the Njemanze probe holding device to include a concave portion that is complementary to the form of the probe because this particular design is amenable to long periods of data collection/use without discomfort to the user while at the same time allowing for reliable data collection (see column 5, lines 35 – 39).

26. Claims 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Njemanze (U.S. patent no. 6,547,737) in view of Barbut et al. (U.S. patent publication no. 20020115982 A1) as evidenced by Slegers (Laser-Doppler Versus Ultrasound Measurements of Pulsatile Flow in a Distensible Tube, WFW reportnr. 95-040, March 1995).

27. Regarding claim 9, Njemanze discloses the limitations of claim 1 as described in paragraph 8 above. However, Njemanze does not disclose that the blood flowmeter probe is a probe for laser Doppler flowmetry. Barbut teaches that cerebral blood flow can be measured using Laser Doppler Flow measurements (see paragraph [0197]). It would have been obvious to a person having ordinary skill in the art at the time of the invention to substitute the ultrasound Doppler probe in the Njemanze invention with a laser Doppler flowmeter (LDF) of Barbut because Slegers teaches that ultrasound and laser Doppler measurements show good agreement when assessing pulsatile flow through tubes (see second paragraph of Abstract, page 3).

28. Regarding Claim 15, Njemanze discloses the blood flow measuring device according to claim 14 wherein the blood flowmeter probe is a probe for ultrasonic-Doppler flowmetry (see column 1, lines 39 – 42). However, Njemanze does not disclose that the blood flowmeter probe is a probe for laser-Doppler flowmetry. Barbut et al. teaches that cerebral blood flow can be measured using Laser Doppler Flow measurements (see paragraph [0197]). It would have been obvious to a person having ordinary skill in the art at the time of the invention to optionally use a laser Doppler flowmeter (LDF) in the Njemanze probe holder because LDFs are capable of measuring cerebral blood flow and Slegers teaches that ultrasound and laser Doppler measurements show good agreement when assessing pulsatile flow through tubes (see second paragraph of Abstract, page 3).

29. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Njemanze (U.S. patent no. 6,547,737) and Barbut et al. (U.S. patent publication no. 20020115982 A1) as evidenced by Slegers (Laser-Doppler Versus Ultrasound Measurements of Pulsatile Flow in a Distensible Tube, WFW reportnr. 95-040, March 1995) as applied to claim 15 above, and further in view of Debow and Colbourne ("Brain temperature measurement and regulation in awake and freely moving rodents" Methods, Jun; 30(2); 167-71). Njemanze and Barbut et al. teach the limitations of claim 15 (see paragraph 28 above). However, neither discloses the use of a temperature sensor with the probe holding device. Debow and Colbourne teach the use of brain telemetry probes to continually measure temperature in various ischemia models (see page 169, section 3.3, paragraph 1, lines 1 - 8). It would have been obvious to a person

of ordinary skill in the art at the time of the invention to include a temperature sensor in the probe holding device because Debow and Colbourne teach that reliance on rectal temperature probes (a common technique at the time of the writing) to estimate brain temperature may not be as accurate as brain temperature monitoring (see Abstract, page 1).

30. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Njemanze (U.S. patent no. 6,547,737) in view of Salmon et al. (U.S. patent no. 6,719,780). Njemanze discloses the limitations of claim 2 (see paragraph 9 above). However Njemanze does not disclose the use of a heating element in the bridging part. Salmon et al. teaches the use of a warming apparatus capable of providing a narrow beam of irradiation to maintain core temperature (see Abstract, lines 1 - 4). It would have been obvious to person of ordinary skill in the art to modify the Njemanze probe holder to include the heating apparatus of Salmon et al. because of it's ability to control core temperature by directing heat at localized areas, particularly areas where a high concentration of arteriovenous anastomoses exist such as the head (see column 2, lines 9 - 21).

31. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clynych (U.S. patent no. 6,463,351) in view of Oxman et al. (U.S. patent no. 5,583,178). Clynych discloses the production process of claim 18 (see paragraph 18 above). However, Clynych does not disclose that the curable material is a silicone resin. Oxman et al. teaches the use of silicone curable compositions (see Field of Invention, column 1, lines 10 - 17. It would have been obvious to a person of ordinary skill in the art at the time of

the invention to use the curable silicone containing compositions of Oxman et al. because they are useful for preparing medical implants (see Field of Invention, column 1, lines 14 – 17).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THO TRAN whose telephone number is (571) 270-1892. The examiner can normally be reached on Mon - Thu, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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